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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/589,358	06/08/2000	Narendra Raghunathji Desai	273012008102	2416

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MORRISON & FOERSTER LLP
3811 VALLEY CENTRE DRIVE
SUITE 500
SAN DIEGO, CA 92130-2332

EXAMINER	
KISHORE, GOLLAMUDI S	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 06/17/2002

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/589,358	Desai
Examiner	**Art Unit**
Gollamudi Kishore	1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Mar 21, 2002* .

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *15-32* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *15-32* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

The request for the extension of time, change of address and the amendment all dated 3-21-02 and the change of address dated 5-22-02 are acknowledged.

Claims included in the prosecution are 15-32.

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 15-32 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 6,074,666. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the reasons set forth before.

Applicants indicate their willingness to file a terminal disclaimer. The rejection is maintained in abeyance.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> **A person shall be entitled to a patent unless --**
>
> **(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.**

4. Claims 15-20 and 30-32 are rejected under 35 U.S.C. 102(e) as being anticipated by Madden (5,389,378).

Madden discloses Benzoporphyrins encapsulated in liposomes for photodynamic therapy of various cancers. The preparation is in a freeze-dried form and contains lactose. Madden teaches the use of a mixture of phospholipids and the lipids include DMPC and PG (note the abstract, col. 5, line 54 through col. 8, line 64, col. 9, lines 1 through line 62, Examples, Example 1 in particular and claims).

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant argues that a review of Madden shows that none of the terms, 'fast breaking', 'blood stream', 'lipoprotein' or 'blood' are used in the patent and that is because there is simply no disclosure by Madden of any liposomal formulation capable of quickly delivering a porphyrin macrocycle to lipoproteins of the blood stream. These arguments are not found to be persuasive since the terms 'fast breaking' and 'rapidly release' without any units are relative terms and applicant has not shown that Madden's

compositions do not behave the same way as instant composition. With regard to applicant's arugment that nothing in Madden teaches or indicates that any of the disclosed liposomal formulations are capable of delivering 90 % of porphyrin macrocycle photosensitizers to lipoproteins, the examiner points out that instant claims do not recite this requirement. Even assuming that they did recite, the examiner points out that since instant claims are composition claims and Madden teaches the same compositions, the burden is upon applicant to show by comparative means that Madden's compositions do not have the same properties. That Madden does not suggest these limitations is not a valid argument.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> **(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.**

6. Claims 15-20 and 26-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thompson (5,277,913) or Kappas (5,010,073) in view of Crowe (4,857,319).

Both Thompson and Kappas teaches liposomal porphyrins and photodynamic therapy (note the abstracts, Examples and claims in each).

What is lacking in these references is the teaching of the presence of sugars.

Crowe teaches that sugars protect liposomes during dehydration and rehydration (note the abstract, examples and claims).

The use of sugars in the liposomes of Thompson, and Kappas would have been obvious to one of ordinary skill in the art since sugars preserve liposomes during dehydration and rehydration steps.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant's arguments regarding this rejection are similar to that put forth for Madden and hence the same response is applicable. Applicant in addition, argues that the references do not teach the compound in claim 25. The rejection of claim 25 is withdrawn. Applicant argues that the ratios claimed are not taught in the references. In response, the examiner points out that ratios are manipulatable parameters and applicant has not shown any criticality. Applicant argues that the references do not teach an inclusion of an antioxidant. The examiner cites the references of Hunt (4,882,165) and Barenholz (4,797, 285) and points out that the inclusion of antioxidants such as BHT to prevent oxidation is known in the art of liposomes (see Example 2 in Hunt; col. 11, line 21 in Barenholz).

7. Claims 15-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Madden as set forth above, OR Thompson (5,277,913) or Kappas (5,010,073) in view of Crowe (4,857,319) as set forth above, further in view of applicant's statements of prior art.

Neither Madden, Thompson or Kappas teach all the porphyrin derivatives in instant claims. Instant specification appear to indicate that the claimed porphyrin

derivatives are known. The use of art known porphyrin derivatives in the liposomes of Madden, or Thompson or Kappas with the expectation of obtaining similar results would have been obvious to one of ordinary skill in the art from the guidance provided by the prior art.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant's arguments once again pertain to the lack of teachings of fast breaking and rapidly releasing nature in the references; these have been addressed above. Applicant further argues that instant rejection provides no showing of why the ordinary skill in the art would find it desirable to use any known porphyrin derivative as part of a liposomal composition. This argument is not found to be persuasive since the references used in the rejection are all directed to liposomes as carriers of porphyrins for the photodynamic therapy and one would expect the liposomes to act the same way irrespective of the type of porphyrin used and applicant has not shown that to be otherwise.

8. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *G.S. Kishore* whose telephone number is (703) 308-2440.

The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-3592.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-1235.

Gollamudi S. Kishore, Ph. D

Primary Examiner

Group 1600

gsk

June 10, 2002